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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,867	01/29/2004	Damon H. DeHart	82162	4117

7590 03/26/2007
KRIEGSMAN & KRIEGSMAN
665 Franklin Street
Framingham, MA 01702

EXAMINER

KOTINI, PAVITRA

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,867	DEHART, DAMON H.	
	Examiner	Art Unit	
	Pavitra Kotini	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 11-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/29/05, 1/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 32-41, 54, 55, 59, 60, drawn to a lancet, classified in class 606, subclass 181.
- II. Claims 11-31, 42-53, 56-58, 61, 63, drawn to a method of manufacturing, classified in class 29, subclass 284.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and II are related as product made and process of making.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make a materially different product such as a scalpel or a suturing needle.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct

- species:
- A. The species of figures 1(a)-(d)
 - B. The species of figures 3(a)-(d)
 - C. The species of figures 4(a)-(d)
 - D. The species of figures 5(a)-(d)
 - E. The species of figures 6(a)-(d)
 - F. The species of figures 7(a)-(d)
 - G. The species of figures 8(a)-(d)
 - H. The species of figures 9(a)-(e)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

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During a telephone conversation with Attorney Weinstein on March 5, 2007 a provisional election was made **without** traverse to prosecute the invention of Group I, Species A, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Lum et al. (US-2001/0027328).

Lum discloses a lancet device comprising:

Regarding **claim 1**, (a) a seamless unitary member (20) which is hollowed along at least a portion of its length (fig. 2), said unitary member including a first end (base of 20), a second end (top of 20), and a longitudinal axis (2A), (b) wherein the first end of said unitary member is shaped to include first and second sharpened tips (22).

Regarding **claim 2**, said seamless unitary member is in the form of a cylindrical tube (fig. 2 and 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lum et al. (US-2001/0027328) in view of Freeman et al. (US-2003/0083686).

Lum discloses (a) a unitary member (20) which is hollowed along at least a portion of its length (fig. 2), said unitary member including a first end (base of 20) and a second end (top of 20), wherein the first end of said unitary member includes first and second sharpened tips (fig. 2), said unitary member is in the form of a cylindrical tube (figs. 2 and 3), wherein said unitary member inherently includes a longitudinal axis, a lateral axis, a vertical axis, a horizontal plane and a vertical plane.

Lum fails to disclose first and second surfaces defining the tips.

However, Freeman teaches (b) first and second ground surfaces (112) which at least partially define the tip, wherein each of said first and second ground surfaces is a planar surface and each of said first and second ground surfaces is a single angle ground surface that extends from the horizontal plane at an acute angle relative to the longitudinal axis and approximately 180 degrees about the longitudinal axis, and wherein said first and second ground surfaces mirror one another about the horizontal plane (figs. 14, 112).

Therefore, it would have been obvious to a person of ordinary skill in the art, at the time of the invention to modify the first and second tips at the first end disclosed by

Lum to include first and second ground surfaces defining the tips as taught by Freeman. Such a modification of changing the tip geometry would provide the benefit of reducing skin tear, penetration force, and pain (para.0157).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. V.D. De Luca (US- 3308822) discloses in figure 11, a needle tip with first and second ground surfaces that are mirror images.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

P. Kotini
AU 3731
3/7/07


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
